

### REMARKS

In the Office Action dated June 5, 2003, claims 1-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Winn et al. in view Gluck et al.

As discussed at the interview, the Winn et al. reference had been previously relied upon by itself by the Examiner as a basis for rejecting the claims of the application, and as explained in Applicants' previous response, the Winn et al. reference is an example of a conventionally operating HFO ventilator, of the type described in the introductory portion of the application. As such, that reference exhibits the problems associated with such a conventionally operating HFO ventilator, as also described in the introductory portion of the present application. The Winn et al. reference employs a piston arrangement to superimpose high-frequency oscillations on a bias flow of gas to a patient. As explained in the present specification, particularly when larger tidal volumes are involved, the mass of air which must be rapidly moved back and forth becomes relatively large, requiring a more powerful oscillator. Moreover, if a more powerful (i.e., higher pressure-producing) oscillator is employed, this results in the walls of the tubing communicating with the patient being slightly stretched or expanded by the higher pressure, and therefore not all of the higher pressure from the oscillator can be used to move the column of air. This has in turn, in conventionally operating systems, required that the tubing system be composed of heavier (stiffer) material, or that the tubing system be mechanically reinforced in some manner.

The present Applicants have found that these problems can be overcome by employing an additional flow of gas which is supplied to and withdrawn from the patient, this flow of additional gas being a different flow from the conventionally-

employed bias flow. Claim 1 explicitly states that a volume of such additional gas is introduced into the flow path for the bias gas, and that at least this same amount of additional gas is withdrawn from the flow path.

As noted above, in Applicants' previous response it was pointed out that the Winn et al. reference, although employing the conventional bias gas flow, does not disclose or suggest the use of an additional gas, in addition to the bias gas flow. This caused the Examiner, in the Final Action, to additionally rely on the Gluck et al. reference, in combination with the Winn et al. reference, as a basis for rejecting claims 1-9 under 35 U.S.C. §103(a).

As also discussed at the interview, the Gluck et al. reference is an example of a ventilator known in the art as a jet ventilator, as described at column 1, line 23 of the Gluck et al. reference. Jet ventilation is also discussed in the introductory portion of the present application at page 1, and is stated to exhibit the same types of problems that are discussed above in connection with HFO ventilation.

In jet ventilation as conventionally understood and as employed in Gluck et al., a series of pressure pulses are supplied to a patient in rapid succession. These pulses, however, are all positive pressure pulses, as can be seen from Figure 4 of the Gluck et al. reference. Therefore, even if these pulses could be considered as an "additional gas" there is no teaching in the Gluck et al. reference to introduce an amount of such an additional gas and to withdraw at least the same amount of the additional gas, as explicitly required in claim 1. Not only is there no teaching in the Gluck et al. reference to do so, but also this is consistent with the conventional understanding of jet ventilation, of which the Gluck et al. ventilator is an example.

Therefore, even if the Winn et al. reference were modified in accordance with the teachings of Gluck et al., a ventilator as set forth in claim 1 still would not result.

As also discussed at the interview, it is equally important that those of ordinary skill in the art consider HFO ventilation and jet ventilation to be two alternative modes of ventilation. Conventionally, either HFO ventilation is prescribed, or jet ventilation is prescribed, and a ventilator operating in the HFO mode is then employed to administer HFO ventilation, or a ventilator operating in the jet ventilation mode is employed to administer jet ventilation. Those of ordinary skill in the art, therefore, without being otherwise instructed or motivated, would have no reason to attempt to "mix" these two different modes of ventilation. A person of ordinary skill in the art, who has not had the benefit of reading the present disclosure, would be deterred from modifying the Winn et al. ventilator in accordance with the teachings of Gluck et al., simply because of the designation in the Gluck et al. reference that the ventilator disclosed therein is a jet ventilator. A person of ordinary skill in the art would have no reason to attempt to modify an HFO ventilator in accordance with structure and operating techniques associated with jet ventilation. If a person of ordinary skill in the art did have the insight to combine portions of these two different modes of ventilation, this would be an insight support patentability, rather than negating patentability.

As noted above, all of the above arguments were presented in the interview conducted on August 5, 2003, and it was agreed at the interview that the claims in their present form were patentably distinguishable over the teachings of Winn et al. and Gluck et al. The Examiner stated that upon submission of a formal response, an

updated search would be conducted, and if no more relevant prior art were located in the updated search, the application would be allowed.

The present response does not introduce any new issues requiring further searching or consideration, and therefore is properly enterable at this stage of prosecution, after the final rejection. Early reconsideration of the application is therefore respectfully requested.

Submitted by,

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